REMARKS

Introductory Comments:

Claims 1-6, 10, 18 and 19 were examined in the Office Action under reply and rejected under (1) 35 U.S.C. §112, first paragraph as nonenabled; and (2) 35 U.S.C. §102. The rejections are believed to be overcome or are respectfully traversed as discussed more fully below.

Overview of the Above Amendments:

Non-elected claims 7-9, 14-17, 20 and 23 have been canceled.

Claims 1, 5 and 6 have been amended to recite that the polypeptide is "isolated" and "immunogenic." Claims 20, 18 and 19 have been amended to recite that the composition is "immunogenic."

Support for the foregoing amendments can be found throughout the specification at, e.g., page 7, lines 15 and 20.

The specification has been amended to denote trademarks by capital letters, to refer to the sequence identifiers as requested by the Examiner, to correct minor typographical errors, and to eliminate reference to colors in the description of the figures.

The foregoing amendments are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications containing the cancelled and/or unamended claims.

Rejoinder:

All currently pending withdrawn method claims depend from the amended composition claims. Thus, applicants request withdrawn claims 13, 21 and 22 be rejoined with the elected claims upon allowance of these product claims.

Formal Matters:

The drawings were objected to because they fail to show indications of color as described in the application. As explained above, the specification has been amended to eliminate references to color and now describes the differences in color in the drawings as white and grey. Thus, this basis for objection has been overcome and withdrawal thereof is respectfully requested.

35 U.S.C. §112, First Paragraph

Claims 1-6, 10, 18 and 19 were rejected under 35 U.S.C. §112, first paragraph as nonenabled. The Examiner argues:

> "[T]he specification while being enabling for pharmaceutical compositions that are immunogenic compositions comprising the polypeptide as set forth in SEQ ID No.51 (elected sequence) does not reasonably provide enablement for pharmaceutical compositions that are vaccine compositions comprising the polypeptide as set forth in SEQ ID No.51 ... The specification has failed to show enablement for a pharmaceutical composition that is a vaccine composition.

Office Action, pages 5-6. However, applicants submit the claims indeed comply with the requirements of 35 U.S.C. §112, first paragraph.

It is seminal patent law with respect to compounds and compositions, "if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention." MPEP 2164.01(c). The Examiner has stated, on the record, that the specification is enabling for immunogenic compositions. For this reason alone, the rejection under 35 U.S.C. §112, first paragraph is improper and should be withdrawn.

Nevertheless, in an effort to advance prosecution, the claims have been amended to recite "immunogenic" polypeptides and compositions, embodiments expressly acknowledged by the Office to be enabled. Thus, the rejection under 35 U.S.C. §112, first paragraph has been overcome and withdrawal thereof is respectfully requested.

35 U.S.C. §102:

Claims 1-6, 10, 18 and 19 were rejected under 35 U.S.C. §102(a) as anticipated by McGillivary et al., 103rd American Society for Microbiology General Meeting, Washington, D.C., May 18-22, 2003 ("McGillivary"). The Office argues McGillivary teaches "a 86-kDa protein in strain F3031 of Haemophilus aegyptius" and that the "protein shares similar domains and at least some notable characteristics with proteins from several other organisms that are known to be important in virulance." The Examiner thus concludes "The amino acid sequence as set forth in SEQ ID NO.51 would be inherent in the teachings of the prior art." Office Action, page 10. However, applicants respectfully disagree with the Examiner's assertions.

In particular, there is absolutely no indication that McGillivary's 86 kDa protein is related to the HadA protein of SEQ ID NO:51. First, as explained in the present specification, the HadA protein shows approximately 40% sequence identity to the *N. meningitidis* NadA protein (see, pages 24-25 of the specification) with the highest degree of homology occurring in the C-terminus. The N-terminus of McGillivary's protein, on the other hand, displays homology to *X. capestris*, *M. Catarrhalis* and *E. coli* proteins. There is no mention in McGillivary of *N. meningitidis* and the authors expressly state that other than the N-terminus, there was no significant match of their protein to any protein sequence in Genbank.

Additionally, the theoretical molecular weight for SEQ ID NO:51 as calculated by two different programs is approximately 27.5 kDa which is well below the molecular weight of McGillivary's protein. See, the appended computations.

Thus, McGillivary's protein does not appear to be the same as applicants'. The Examiner is reminded that in order to establish inherency, the missing descriptive matter must **necessarily** be present in what is described in the reference and this **must** be recognized by one of ordinary skill in the art. See, e.g., *In re Robertson*, 49 USPQ2d 1949 (Fed. Cir. 1999); and *Transclean Corp. v. Bridgewood Serv. Inc.*, 62 USPQ2d 1865, 1871 (Fed. Cir. 2002). The mere fact that a certain result may occur from a given set of

circumstances is not a sufficient basis for a §102 rejection. See, e.g., *Scaltech Inc. v. Retec/Tetra L.L.C.*, 51 USPQ2d 1055 (Fed. Cir. 1999); *In re Robertson*, 49 USPQ2d 1949 (Fed. Cir. 1999); and *Trintec Indus. Inc. v. Top-U.S.A. Corp.*, 63 USPQ2d 1597 (Fed. Cir. 2002).

There is absolutely no indication in McGillivary that the 86 kDa protein is the same as the claimed HadA protein of SEQ ID NO:51 and applicants submit one of skill in the art would certainly not recognize this to be the case from a reading of McGillivary. Rather, the opposite conclusion would be drawn based on the fact that McGillivary's protein displayed no homology in its C-terminus to known sequences in Genbank and the theoretical molecular weight of the HadA protein is much lower than McGillivary's.

For the reasons presented above, McGillivary is not believed to anticipate the present invention and withdrawal of this basis for rejection is respectfully requested.

Claims 1-6, 10, 18 and 19 were rejected under 35 U.S.C. §102(b) over Smoot et al., *Infect. Immun.* (2002) 70:2694-2699 ("Smoot"). The Examiner points to Table 3 of Smoot as evidencing that the reference teaches "proteins that are homolog to *N. meningitiditis*" and that the present specification discloses "an alignment of the HadA protein with the NadA protein." Office Action, page 11. However, as with McGillivary, Smoot is not believed to anticipate the claimed invention.

Table 3 of Smoot presents only two *N. meningitiditis* homologs to their ORFs 1 and 2. As shown in Table 3, these ORFs encode proteins that are 3,371 and 166 amino acids in length, respectively, and that have molecular weights of 42.7 and 18.8, respectively. The protein of SEQ ID NO:51, on the other hand, includes 256 amino acids and has a theoretical molecular weight of 27.5. Hence, Smoot's proteins, as with McGillivary's, do not appear to be the same as applicants'.

The law is clear that in order to anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986). *Atlas Powder Co. v. E. I. du Pont De Nemours & Co.*, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the

claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983). Finally, the law requires identity between the claimed invention and the prior art disclosure. *Kalman v. Kimberly-Clar Corp.* 218 USPQ 2d 781, 789 (Fed. Cir. 1983, cert. denied, 465 U.S. 1026 (1984)).

Since Smoot does not teach each and every element of the claims, it cannot anticipate the present invention. Thus, withdrawal of the basis for rejection under 35 U.S.C. §102(b) is respectfully requested.

CONCLUSION

Applicants submit that the claims define a patentable invention and that a Notice of Allowance is therefore in order. If the Examiner notes any further matters which may be resolved by a telephone interview, the Examiner is encouraged to contact the undersigned by telephone at 650-493-3400.

Please direct all further written communications in this application to:

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Respectfully submitted,

Date: 9/17/09 By: _____

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Compute pI/Mw

Theoretical pI/Mw (average) for the user-entered sequence:

```
        10         20         30         40         50         60
MKRNLLKQSV IAVLIGGTTV SNYALAQAQA QAQVKKDELS ELKKQVKEMD AAIDGILDDN
        70         80         90        100        110        120
IAYEAEVDAK LDQHSAALGR HTNRLNNLKT IAEKAKGDSS EALDKTEALE EQNDEFLADI
       130        140        150        160        170        180
TALEEGVDGL DDDITGIQDN ISDIEDDINQ NSADIATNTA AIATHTQRLD NLDNRVNNLN
       190        200        210        220        230        240
KDLKRGLAAQ AALNGLFQPY NVGKLNLTAA VGGYKSQTAV AVGTGYRYNE NIAAKAGVAF
       250
THGGSATYNV GVNFEW
```

Theoretical pI/Mw: 4.63 / 27462.34

science gateway

Tools: Protein Molecular Weight Calculator

Protein Molecular Weight accepts a protein sequence and calculates the molecular weight. You can append copies of commonly used epitopes and fusion proteins using the supplied list. Use Protein Molecular Weight when you wish to predict the location of a protein of interest on a gel in relation to a set of protein standards.

Paste the raw or FASTA sequence into the text area below.

```
MKRNLLKQSVIAVLIGGTTVSNYALAQAQAQAQVKKDELSELKKQVKEMDAA
IDGILDDNIAYEAEVDAKLDQHSAALGRHTNRLNNL
KTIAEKAKGDSSEALDKTEALEEQNDEFLADITALEEGVDGLDDDITGIQDNI
SDIEDDINQNSADIATNTAAIATHTQRLDNLDNRV
NNLNKDLKRGLAAQAALNGLFQPYNVGKLNLTAAVGGYKSQTAVAVGTGYRY
NENIAAKAGVAFTHGGSATYNVGVNFEW
```

SUBMIT CLEAR

Add 1 copies of Nothing to the above sequence.

The Sequence Manipulation Suite: Protein Molecular Weight

Results for 256 residue sequence starting "MKRNLLKQSV".

The protein weighs **27.47** kilodaltons